

## § 482.68

## 42 CFR Ch. IV (10–1–15 Edition)

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[72 FR 60788, Oct. 26, 2007]

### § 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72

through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation specified in §§ 482.1 through 482.57.

### § 482.70 Definitions.

As used in this subpart, the following definitions apply:

*Adverse event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a beneficiary.

*End-Stage Renal Disease (ESRD)* means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

*ESRD Network* means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

*Heart-Lung transplant center* means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

*Intestine transplant center* means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

*Network organization* means the administrative governing body to the network and liaison to the Federal government.

*Pancreas transplant center* means a Medicare-approved kidney transplant

center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

*Transplant center* means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

*Transplant hospital* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

*Transplant program* means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

#### GENERAL REQUIREMENTS FOR TRANSPLANT CENTERS

##### **§ 482.72 Condition of participation: OPTN membership.**

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

##### **§ 482.74 Condition of participation: Notification to CMS.**

(a) A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information

for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's "primary transplant surgeon" or "primary transplant physician;"

(2) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(3) Inactivation of the transplant center.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

[72 FR 15273, Mar. 30, 2007, as amended at 79 FR 27155, May 12, 2014]

##### **§ 482.76 Condition of participation: Pediatric Transplants.**

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at § 488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger